इंटरनेट मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

"जानने का अधिकार, जीने का अधिकार"
Mazdoor Kisan Shakti Sangathan
"The Right to Information, The Right to Live"

"पुराने को छोड नये के तरफ"
Jawaharlal Nehru
"Step Out From the Old to the New"

IS 13928 (1993): Rigid contact lenses - Requirements [MHD 5: Ophthalmic Instruments and Appliances]

"ज्ञान से एक नये भारत का निर्माण"
Satyanarayan Gangaram Pitroda
"Invent a New India Using Knowledge"

Act Number 22 of 2005
The Indian Parliament
RIGHT TO INFORMATION

Made Available By
Public.Resource.Org

"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

BLANK PAGE

BRUTUM FULMEN

IGNORANTIA JURIS NON EXCUSAT

PROTECTED BY COPYRIGHT

भारतीय मानक

दृढ़ कान्टेक्ट लैंस – अपेक्षाएँ

Indian Standard

RIGID CONTACT LENSES — REQUIREMENTS

UDC 681·735

© BIS 1993

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

December 1993

Price Group 6

Ophthalmic Instruments and Appliances Sectional Committee, MHD 5

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Ophthalmic Instruments and Appliances Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

In view of the fact that the use of contact lens is becoming increasingly popular and a number of users, manufacturers and ophthalmic prescribers in our country are involved with the rigid contact lens, it was felt necessary to standardize basic nomenclature and to specify limits of tolerances for measurement and performance of these lenses. The purpose of this standard is to include those lenses made from plastic materials that have been widely accepted by the industry. Annex A gives the recommended method for specification of contact lenses.

This standard is based on the American National Standard 280.2-1972 issued by the American National Standards Institute, New York.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

RIGID CONTACT LENSES — REQUIREMENTS

1 SCOPE

1.1 This standard covers the requirements for rigid (hard) corneal and scleral contact lenses made from plastic materials (for example, polymethylmethacrylate, cross-linked polymethylmethacrylate, cellulose acetate butyrate, polyacrylate/silicone copolymers, silicone, butyl styrene, and related materials) with spherical and nonspherical surfaces.

1.2 Where applicable, this standard also applies to multifocal lenses, lenses with prism components, tinted lenses, and contact lens containers. This standard applies not only to new lenses but also to lenses modified by the supplier or by the practitioner. However, it is not the intention of this standard to prevent the practitioner from altering lenses according to the needs of the individual patient.

2 GLOSSARY OF TERMS AND DEFINITIONS

2.1 Terms Applying to Corneal Lenses (*see* Fig. 1).

2.1.1 *Anterior Peripheral Curve* (γ_{a1}).

The most peripheral curve on the anterior surface of the lens.

2.1.2 *Blend*

An alternation of a transition zone (junction) :

a) with curves of discernible radii

b) with confluent curves

2.1.3 *Centre Thickness* (t_c)

The thickness at the geometrical centre of a lens, specified in millimetres.

2.1.4 *Diameter* (ϕ_r)

The greatest linear distance across a lens specified in millimetres.

2.1.5 *Edge*

The junction of the anterior and posterior peripheral curves of a lens.

2.1.6 *Lens Identification*

If an identifying dot is used, it shall be placed on the right lens. When an identifying dot is placed on a lens having a reference axis, for example, a lens having a prism ballast, the dot shall be placed on the reference axis. When both lenses are to be dotted, the right lens shall have one dot, and the left lens shall have two dots.

2.1.7 *Optic Zone, Anterior or Posterior*

That zone of a lens surface which is optically effective, that is, contributes to the refracting power of the lens.

2.1.8 *Optic Zone Diameter, Anterior* (ϕ_{ao}) *or Posterior* (ϕ_e)

The greatest linear distance across the anterior or posterior optic zone of a lens, specified in millimetres.

2.1.9 *Peripheral Curve Radius* (r_1, r_2, r_3, *etc*)

The radius of a peripheral curve, anterior or posterior, specified in millimetres.

2.1.10 *Peripheral Curve Width*

The width of a peripheral curve, anterior or posterior, specified in millimetres.

2.1.11 *Posterior Central Curve* (*Base Curve*) (r_0)

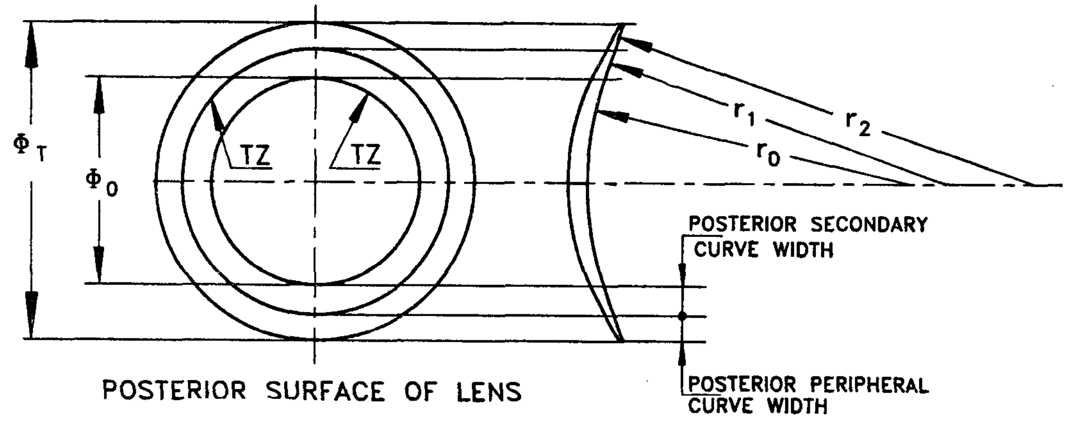
The posterior surface curve (or curves in the case of toric surfaces) that corresponds to the optic zone of the lens, radius of curvature specified in millimetres.

2.1.12 *Posterior Intermediate Curve*

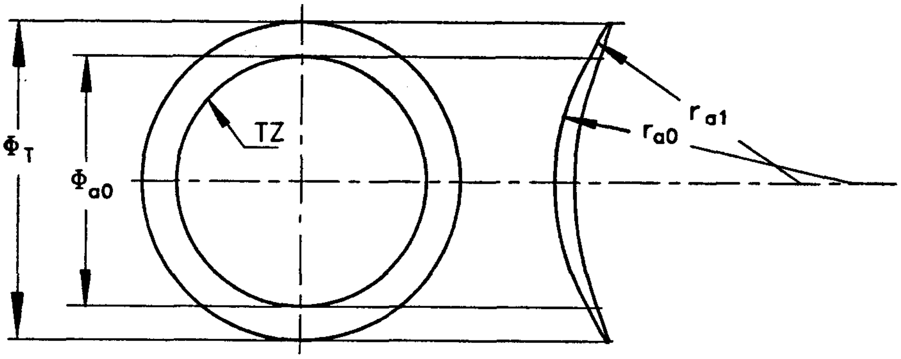
A posterior surface curve that lies between the central curve and the peripheral curve, radius of curvature specified in millimetres:

a) If the posterior surface has three curves, this term may be used synonymously with the term secondary curve.

b) If the posterior surface of a lens has more than three curves, there will be more than one intermediate curve; for example, the posterior surface may have a central curve, intermediate curve No. 1, intermediate curve No. 2, intermediate curve No. 3 and a peripheral curve (bevel).


Φ_T
Φ_0
TZ
TZ
r_1
r_2
r_0
POSTERIOR SECONDARY CURVE WIDTH
POSTERIOR PERIPHERAL CURVE WIDTH

POSTERIOR SURFACE OF LENS



ANTERIOR SURFACE OF LENS

Symbols for Dimensions

Dimensions	*Symbol*	*Dimensions*	*Symbol*
r_0	Posterior central curve radius	ϕ_{a1}, ϕ_{a2}, etc	Anterior optic zone diameters centre thickness
r_1, r_2, etc	Posterior peripheral curve radii		
ϕ_0	Posterior central optic zone diameter	t_c	Centre thickness
ϕ_r	Diameter	t_{suffix}	Carrier junction thickness (suffix to indicate junction concerned, for example, t_{a0})
r_{a0}	Anterior central optic curve radius		
r_{a1}, r_{a2}, etc	Anterior peripheral curve radii		
ϕ_{a0}	Anterior central optic zone diameter	*TZ*	Transition zone

FIG. 1 CORNEAL LENS TERMINOLOGY

2.1.13 *Posterior Peripheral Curve (Bevel)*

The most peripheral and flattest curve on the posterior surface of the lens, radius and width specified in millimetres.

2.1.14 *Posterior Secondary Curve*

A posterior surface curve that is adjacent to and flatter than the central curve, radius and width specified in millimetres.

2.1.15 *Rigid Contact Lens*

A corneal contact lens that maintains its shape without the influence of external forces.

2.1.16 *Transition Zone*

The junction between two adjacent curves on the anterior or posterior surface of a lens.

2.1.17 *Truncated Lens, Diameters*

The shortest and longest distances across the lens.

2.2 Terms Applying to Scleral Lenses

2.2.1 *Anterior Optic Zone* (ϕ_{ao})

That portion of the anterior surface which is optically effective, lying within the corneal portion of the lens.

2.2.2 *Anterior Surface*

The front surface of the contact lens.

2.2.3 *Apical Clearance*

The clearance between the apex of the cornea and the posterior corneal portion of the lens.

2.2.4 *Channelled Lens*

A scleral lens with one or more channels on the posterior scleral portion extending beyond the transition to aid interchange of tears and respiration of the globe.

2.2.5 *Corneal Portion*

That anterior or posterior portion of the lens which lies over the cornea.

2.2.6 *Fenestrated Lens*

A scleral lens that has one or more holes which serve the same function as the channels described in 'channelled lens'.

2.2.7 *Fluid Scleral Lens*

A scleral lens, not fenestrated or channelled, into which an added solution is placed in the corneal portion.

2.2.8 *Impression Lens*

A scleral lens that has been fabricated from the case of the impression of the eye.

2.2.9 *Lacrimal Lens*

The lens formed by the lacrimal (tear) layer lying between the cornea and the central optic portion.

2.2.10 *Lens Identification*

Lenses are identified with one dot on the right lens and two dots on the left, placed at the 6 o' clock position.

2.2.11 *Preformed Scleral Lens*

A scleral lens whose posterior surfaces are of some predetermined form.

2.2.12 *Posterior Optical Zone* (ϕ_o)

That portion of the posterior surface which is optically effective, lying within the corneal portion of the lens.

2.2.13 *Posterior Surface*

The portion of the contact lens lying in apposition with the eyeball.

2.2.14 *Scleral Cosmetic Lens* (*Prosthetic Scleral Shell*)

A scleral contact lens specifically designed to change or to improve the appearance of the eye.

2.2.15 *Scleral Lens*

A contact lens whose main bearing section rests upon the sclera of the eye.

NOTE — In the contact literature, the term 'haptic lens' is often used interchangeably with 'scleral lens'.

2.2.16 *Scleral Portion*

The anterior and posterior portion of the lens that lies over the sclera.

2.2.17 *Specifications*

The aggregate of essentials that determine the construction of finished contact lens.

2.2.18 *Transition*

The zone between the posterior corneal and posterior scleral portions of the lens.

2.3 Terms Applying to Instrumentation and Measurement

2.3.1 *Focimeter* (*Lensometer, Vertometer*)

An instrument used to determine the vertex power of a lens, in air.

2.3.2 *Measuring Magnifier*

A hand-held magnifier with a reticule scale, calibrated in 0·1 mm steps.

2.3.3 *Moire Fringe Instrument*

An instrument utilizing moire fringe patterns in order to measure surface curvatures and evaluate asphericity.

2.3.4 *Ophthalmometer* (*Keratometer*)

An instrument for measuring the anterior curvature of the cornea, consisting of a luminous pattern of mires whose images, produced by reflection in the cornea, are viewed through a telescope with which is combined a doubling and image size measuring system.

2.3.5 *Optical Microspherometer* (*Radiuscope*)

An instrument used for directly determining the radii of curvature of a contact lens surface by measuring the distance between the lens surface and the centre of curvature, specified in millimetres.

2.3.6 *Posterior (Back) Vertex Power, in Dioptres*

The reciprocal of the distance, in metres, from the posterior surface of a lens to the secondary focal point, measured in air.

2.3.7 *Shadowgraph (Projection Magnifier)*

A device that affords high magnification, providing shadows rather than direct views. It is used for the inspection of lens edges and surfaces.

2.4 Terms Applying to Containers and Storage

2.4.1 *Cleaning-Storage Containers*

Devices designed to accomplish effective cleaning as well as storage of contact lenses.

2.4.2 *Dry Storage*

Storage of contact lenses in a closed, vented, or open chamber in the absence of any added storage solution.

2.4.3 *Mailing Containers (Mailers)*

Devices designed for transferring lenses from the laboratory to the practitioner. These devices are designed to have high impact strength and a low profile so as to enhance safe mail delivery of lenses.

2.4.4 *Mould Release Agents*

Chemicals employed in the automatic moulding of plastic components to prevent the formed plastic from adhering to the mould. Agents, such as, silicones, fatty acids, and fatty salts are sometimes used for this purpose.

2.4.5 *Storage Containers*

Containers specially designed for safe storage of contact lenses when they are not being worn.

2.4.6 *Wet Storage*

Storage of contact lenses completely submerged in a liquid product specially formulated for this purpose, containing a germicidal preservative system.

3 LENS REQUIREMENTS

3.1 The lens requirements shall be as given in Tables 1 and 2.

4 OPTICAL PERFORMANCE

4.1 Plastic Materials for Lens Stock

4.1.1 *Optical Quality*

No bubbles, striae, waves, grayness, or inhomogeneities that will impair visual performance or comfort shall be visible when the lens is qualitatively viewed before a diffusely illuminated background. A magnification of 10 X accepted shall be past for this inspection.

4.1.2 *Light Transmission*

4.1.2.1 *Clear plastic*

Transmission should not be less than 88 percent of visible light energy at a thickness of 0·10 mm.

4.1.2.2 *Coloured plastic*

Material should be tinted with inert pigment which is diffusely and uniformly spread throughout the plastic.

4.1.3 *Refractive Index*

There shall be uniformity of index of refraction throughout the material and stability of the refractive index in air. Variation of index of refraction shall be not greater than 0·5 percent from the specified index.

4.1.4 *Physical Properties*

The material shall be machinable and polished easily in case of lathed lenses and shall have strength and stability.

4.2 Optical Properties of Finished Lenses

4.2.1 *Surface Optical Quality of Lenses*

4.2.1.1 *Physical inspection*

No pits, scratches, or chips should be present that will impair visual performance or comfort. A magnification of 10X under proper illumination shall be accepted for this inspection (*see* **4.1.1**).

4.2.1.2 *Inspection of surface curvature*

Inspection should be conducted with an instrument that measures surface curvature directly and over small zones. A microspherometer is suitable for this purpose.

4.2.1.2.1 *Anterior lens surface*

Measure with a microspherometer at various points from centre to edge of the optic zone in several meridians. Tolerances should include curvature variations on spherical surfaces not greater than ± 0·02 mm (total variation of 0·04 mm) in minus lenses and ± 0·01 mm (total variation of 0·02 mm) in plus lenses.

Table 1 Requirements for Corneal Lenses

(*Clause* 3.1)

(All measurements are made in air with lenses in an air-dried state. For testing procedures, *see* **5**).

Parameter	Tolerance	
	Conventional*	Gas Perm†
Diameter (ϕ_T)	±0·05 mm	±0·05 mm
Posterior optic zone diameter (ϕ_0)		
a) Light blend	±0·10 mm	±0·010 mm
b) Medium or heavy blend	±0·20 mm	±0·20 mm
Posterior central curve (base curve) radius (r_0)	±0·025 mm	±0·050 mm
Posterior secondary, intermediate or peripheral curve width		
a) Light blend	±0·05 mm	±0·05 mm
b) Medium or heavy blend	±0·10 mm	±0·10 mm
Posterior secondary (r_1), intermediate (r_2), or peripheral (r_n) curve radius	±0·10 mm	±0·10 mm
Anterior peripheral curve (r_{a0})	±0·20 mm	±0·20 mm
Anterior optic zone diameter (ϕ_{a0})	±0·10 mm	±0·10 mm
Refractive power (F/V[1,2,3])		
a) 0·0 to 5	±0·12 D	±0·12 D
b) 5·12 to 10	±0·18 D	±0·18 D
c) 10·12 to 15	±0·25 D	±0·25 D
d) 15·12 to 20	±0·37 D	±0·37 D
e) Over 20	±0·50 D	±0·50 D

	Tolerance	
	Conventional*	Gas Perm†
Prism power (measured from the geometric centre)[3]		
a) 0·0 to 10	±0·25 d	±0·25 d
b) Over 10	±0·50 d	±0·50 d
Cylinder power [3,5]		
a) Up to 2	±0·25 D	±0·25 D
b) 2 to 4	±0·37 D	±0·37 D
c) Over 4	±0·50 D	±0·50 D
Cylinder axis	±5	±5
Toric base curve radii		
a) dd r_0 0 to 0·20 mm	±0·02 mm	±0·05 mm
b) dd r_0 0·21 to 0·40 mm	±0·03 mm	±0·06 mm
c) dd r_0 0·41 to 0·60 mm	±0·05 mm	±0·07 mm
d) dd r_0 more than 0·60 mm	±0·07 mm	±0·09 mm
Bifocal refractive power addition[2,3]	±0·25 D	±0·25 D
Bifocal segment height	−0·10 mm +0·20 mm	−0·10 mm +0·20 mm
Centre thickness (t_c)[4]	±·02 mm	±·02 mm
Edges	As specified (*see* Annex B)	
Colour	Pigment inert and uniformly distributed	
Optical quality and surface quality	*see* **4.1.1** and **4.2.1.1**	

---

*Polymethylmethacrylate, cross linked polymethylmethacrylate, and related materials.

†Cellulose acetate butyrate, polyacrylate/silicone copolymers, silicone, butyl styrene and related materials.

[1] If a lens is supplied to meet ordered specifications, and the lens base curve and power errors are cumulative (that is, base curve and lens power errors both add plus power or both add minus power to the refractive correction), the cumulative error shall not exceed 0·25 D.

[2] When a pair of lenses are supplied to ordered specifications, the cumulative errors in power between the right and left lenses shall not exceed 0·25 D.

[3] Symbols used are as follows:

D = dioptres,
d = prism dioptres, and
dd = difference between radii of principal meridians.

[4] When a pair of lenses is supplied to ordered specifications, the algebraic differences in thickness error between right and left lenses shall not exceed 0·02 mm.

[5] For measurement purposes, sphero-cylindrical powers shall be transformed to meridonial powers and the tolerance applied to each individual power.

Table 2 Requirements for Scleral Lenses

(*Clause* 3.1)

(All measurements are made in air with lenses in an air-dried state. For testing procedures, *see* **5**.)

Parameter	Tolerance
a) Outside diameter (size) (ϕ_r)	± 0·25 mm
b) Posterior central curve (base curve) radius (r_0)	± 0·10 mm
c) Refractive power (F'_v)[1,2,3]	
1) 0·0 to 5	± 0·12 D
2) 5·12 to 10	± 0.18 D
3) 10·12 to 15	± 0·25 D
4) 15·12 to 20	± 0·37 D
5) Over 20	± 0·50 D
d) Prism power (measured from the geometric centre)[3]	
1) 0·0 to 6	± 0·25 d
2) Over 6	± 0·50 d
e) Cylinder power[3,4]	
1) Up to 2	± 0·25 D
2) 2 to 4	± 0·37 D
3) Over 4	± 0·50 D
f) Cylinder axis	± 5
g) Centre thickness (t_c)	± 0·03 mm
h) Antrior central curve radius (r_{ao})	± 0·01 mm
j) Edges	Well polished and rounded
k) Surface quality	*See* **4.2.1.1**
m) Transition	As specified
n) Fenestration	As specified
p) Clearance	As specified, within ± 0·02 mm

[1] If a lens is supplied to meet ordered specifications, and the lens base curve and power errors are cumulative (that is, base curve and lens power errors both add plus power or both add minus power to the refractive correction), the cumulative error shall not exceed 0·25 D.

[2] When a pair of lenses is supplied to ordered specifications, the cumulative errors in power between the right and left lenses shall not exceed 0·25 D.

[3] Symbols used are as follows:

D = dioptres, and
d = prism dioptres.

[4] For measurement purposes, sphero-cylindrical powers shall be transformed to meridonial powers and the tolerance applied to each individual power.

4.2.1.2.2 *Posterior lens surfaces*

Measure with a microspherometer as described above. A tolerance of ± 0·025 mm variation in curvature is acceptable optically for both plus and minus lenses.

4.2.2 *Refractive Power*

Posterior (back) vertex power is recommended as the standard specification in order to correspond to the ametropia of the eye in the corneal plane. This specification is particularly necessary in high plus corrections, however, the focimeter must be adapted properly to measure the posterior vertex power (*see* **5.7**).

4.2.3 *Contrast Transmission*

During measurement of refractive power, the quality of the target image should be examined. There shall be no degradation of target detail and no doubling of the image.

5 TESTING PROCEDURES

5.1 The accuracy of any measuring instrument shall exceed the prescribed tolerance by a margin of at least two.

5.2 Diameter

The corneal lens diameter may be measured by means of a slowly varying V-channel gauge, a 10X measuring magnifier or a projection magnifier; scleral lens outside diameter is measured across the posterior scleral flange, using a millimetre ruler.

5.3 Posterior Optic Zone Diameter

Measured by means of a 10X measuring magnifier or a projection magnifier.

5.4 Posterior Central Curve (Base Curve) Radius

Measured by means of an optical microspherometer, the instrument having been zeroed and calibrated within ± 0·01 mm.

An ophthalmometer may be used for this purpose and for evaluating aspheric surface if provision is made for rotating the lens and moving it from side to side so that the whole poserior central zone (optic zone) of the lens may be viewed.

5.5 Posterior Secondary, Intermediate, or Peripheral Curve Width

It is measured by means of a 10X measuring magnifier or projection magnifier.

5.6 Posterior Secondary, Intermediate, or Peripheral Curve Radii

Although it is desirable to objectively measure these radii, presently available instrumentation does not make this possible. However, a moire fringe instrument can be used to estimate those parameters.

5.7 Transition Zone Blending Curve Radius

As above, this cannot be measured with presently available instrumentation.

5.8 Refractive Power

All refractive power measurements are specified and measured as posterior vertex power which is measured by means of a conventional focimeter. The posterior surface of the lens is placed against the lens top in the same plane in which the posterior surface of the spectacle lens lies when being measured in a focimeter. The focimeter aperture should be approximately 6 mm in diameter, and during measurement the lens should not be hand-held.

5.9 Prism Power

The prism power should be measured by marking the geometrical centre of the lens, and then measured in the focimeter.

5.10 Cylinder Power

Measure posterior vertex power of sphero-cylindrical lens with a focimeter. For bitoric lenses, verify base curve prior to measuring cylinder power.

5.11 Cylinder Axis

Determine the cylinder axis with posterior surface of the lens against lens stop of focimeter. For a prism ballast front surface toric lens, the cylinder axis is measured with the prism base down and the base-apex line 90 degrees : for a bitoric lens the cylinder axis is measured with respect to the orientation of the flat meridian of the posterior toric surface.

5.12 Toric Base Curve Radii

Radii of two principal meridians of the posterior optic zone are measured by means of an optical microspherometer (*see* 5.3).

5.13 Bifocal Refractive Power Addition

Back vertex power is measured using a focimeter.

5.14 Bifocal Segment Height

Measured by means of a 10X measuring magnifier or a projection magnifier.

5.15 Centre Thickness

A dial thickness gauge that is calibrated in units of 0·01 mm and reads accurately to 0·005 mm may be used.

5.16 Edges

At present there is no mechanical device available for measuring the edge thickness but edge thickness and shape may be evaluated by means of a projection magnifier, or by examination in a powerful focussed light under 20X magnification, preferably binocular (*see* Annex B).

5.17 Anterior Peripheral Curve Radius

There is no appropriate instrumentation available at present. However, a moire fringe instrument can be used to estimate this parameter.

5.18 Anterior Peripheral Curve Width

Measured by means of a 10X measuring magnifier or a projection magnifier.

5.19 Anterior Optic Zone Diameter

Measured by means of a 10X measuring magnifier or a projection magnifier.

5.20 Inspection for Optical Quality and Surface Quality

The contact lens surface should be examined in a powerful focussed light under 10X magnification, preferably binocular.

5.21 Inspection of Anterior Optic Zone for Uniform Curvature

The use of an optical microspherometer is recommended.

5.22 Colour

The lens should be inspected with a binocular microscope, using a magnification of 25X and diffuse background illumination.

5.23 Scleral Lens Transition

Inspected under 10X magnification.

5.24 Scleral Lens Fenestration

Inspected under 10X magnification. Posterior and anterior peripheral surface of hole shall be tapered.

6 STORAGE DEVICES

6.1 Construction Materials

6.1.1 Materials should be inert so as not to react with, or add to, the solutions used for cleaning and storage of contact lenses. Materials should not release anything into the storage solution, nor should the material absorb anything from the storage solution; there should be no 'in' or 'out' effects. (Some examples of presently available plastics that meet such criteria are polypropylene, polyethylene, polystyrene, and the like. An example of a plastic material that does not meet such criteria would be phenolformaldehyde which releases phenol.)

6.1.2 If a mould release agent is used, it should be nontoxic and non-reactive with the lens materials.

6.1.3 It is desirable that the materials used, particularly in areas of storage container that are in direct contact with the lens, should be of a plastic softer than the lens material to lessen the risk of scratches when the surfaces come into contact.

As important as softness of the materials, the physical characteristics of the container should be such that all surfaces are smooth so as to eliminate rough edges that could scratch the lenses (for example, polystyrene, although harder than polymethylmethacrylate, has been used in the construction of a storage container without any discernible side effects because all edges of the container are smooth). Conversely, rough edges of containers fabricated from polyethylene or polypropylene can damage a contact lens even though these plastics are softer than the usual lens materials.

6.1.4 Materials should be durable and of high impact strength to prevent crushing or shattering, and to offer maximum protection to the lenses.

6.1.5 Material should meet the criteria established for extractables from plastic containers (*see* U. S. Pharmacopoeia, Revision XXI, National Formulary, 16th *Ed*, 1985, Ch 661, Containers).

6.2 Hygienic Cleaning

6.2.1 Hygienic cleaning of storage devices is practical and possible but sterilization, specially sterilization of the outer surface of storage devices, is not possible.

6.2.2 The physical characteristics of the case should be simple in design so as to facilitate cleaning. All inner surfaces of the case should be smooth and easily accessible. Curved surfaces facilitate more effective cleaning.

6.2.3 Storage cases should be composed of materials that will not react with ultraviolet light since most patients may choose to 'sterilize' lenses in this manner.

6.3 Materials Other Than Plastic in Storage Containers

6.3.1 Materials, such as, sponge rubber which might react with the preservatives in storage solutions, should not be used.

6.3.2 Metal components, for example, screens, springs and the like, should be of material that will not interact with preservatives in the storage solutions.

6.4 Size of Storage Container

6.4.1 Storage cases should be large enough to contain an adequate volume and concentration of solution to kill potential contaminants.

6.4.2 Storage cases should be designed so that the storage solution can completely submerge the lens no matter in what position the storage case is oriented.

6.4.3 The storage case should have chambers of adequate depth and design so that the breakage of lenses is minimized.

6.4.4 There should be no scissors action that might warp or break the lens when the container is closed.

6.5 Coding

6.5.1 Since many contact lens patients, specially aphakic patients have poor visual acuity, identification of right and left compartments is desirable.

6.5.2 Colour coding can be used with distinct colours designating the lens compartments for the right and left lenses. It is desirable to use a white colour for the right lens container cover. The colour of the container should be such that the tinted lenses can be readily seen within the container. For example, white containers readily show tinted lenses.

6.5.3 Tactile coding is very desirable for partially sighted individuals. An acceptable method of tactile coding is the use of raised letters, R and L, of sufficient size so that an individual can detect R and L compartments. Another acceptable tactile method is to use a different shape for right and left compartments; one round component for right and one square component for left.

6.6 Leakage

6.6.1 Storage cases should be constructed to be as leakproof as possible.

6.6.2 The closure of the case should be easily manipulated so as to prevent leakage.

6.7 Lens Holding Devices Within the Storage Container

6.7.1 Lens holding devices within the storage container should be composed of material softer than the lens material. In the design of holding devices, physical restraint through pressure points on any segment of the lens should be avoided to minimize warpage.

6.7.2 Lens holding devices should be of adequate size so that there is free access of solution to all surfaces of the lens.

ANNEX A

(*Foreword*)

RECOMMENDED METHOD FOR THE SPECIFICATION OF CONTACT LENSES

(This Annex is not a part of this standard but is included for information only)

A-1 SPECIFICATIONS (to be listed in the following order)

a) Posterior central curve radius (base curve) (r_0);

b) Refractive power ($F'v$);

c) Diameter ($\phi_{\tau r}$);

d) Centre thickness (t_c);

e) Secondary curve (r_1) beginning with the posterior optic zone diameter (ϕ_0);

f) Additional peripheral curves (r_1, r_2, etc) over their respective optic zones (ϕ_1, ϕ_2, etc) or widths;

g) Lens material and colour; and

h) Additional notes, that is, anterior optic zone (ϕ_{a0}), prism information, type of transition zone, edge description, etc.

A-1.1 An alternate method for the prescription of contact lenses is as follows:

a) Posterior central curve radius (base curve) (r_0) and peripheral optic zone diameter (ϕ_0) written as $r_0 : \phi_0$;

b) Secondary curve (r_1) and first peripheral curve optic zone diameter (ϕ_1) written as $r_1 : \phi_1$; and

c) Peripheral curves (r_2) and next peripheral curve optic zone diameter (ϕ_2) written as $r_2 : \phi_2$, etc.

These may be 'strung out' as follows:

$R_0 : \phi_0/r_1 : \phi_1/r_2 : \phi_2/r_3 : \phi_\tau$

d) Refractive power ($F'v$);

e) Anterior central zone diameter (ϕ_{a0}), if applicable;

f) Lens material and colour; and

g) Additional notes, that is, anterior optic zones (ϕ_{a1}), prism information, type of transition zone, edge description, etc.

A-2 EXAMPLES OF LENSES

A-2.1 Tri-Curve Corneal Lens with Fenestration

7·50	r_0	Posterior central curve
$-3\cdot0$	$F'v$	Refractive power
9·3	ϕ_τ	Diameter
0·16	t_c	Centre thickness
9·0/7·6	r_1/ϕ_0	Secondary curve and optic zone diameter
11·0/8·9	r_2/ϕ_1	Peripheral curve and peripheral zone diameter

Blue Pmma

1 fenestration 0·3 mm, 2·0 mm from edge

or

7·50 : 7·60/9·00 : 8·90/11·00 : 9·3 $r_0 : \phi_0/r_1 : \phi_1/r_2 : \phi_\tau$

$-$ 3·00, 0·16 $F'v$, t_c

Blue Pmma

1 fenestration 0·3 mm, 2·0 mm from edge

A-2.2 Corneal Lens with Back Toroidal Surface

8·10/7·50	r_{01}/r_{02}
$-3\cdot00$	$F'v$
9·3	ϕ_τ
0·15	t_c
9·40/8·80	r_{11}/r_{12}
7·50	ϕ_0
11·3/10·7	r_{21}/r_{22}
8·9	ϕ_1

Blue Pmma

or

$\frac{8\cdot10}{7\cdot50} : 7\cdot50/\frac{9\cdot40}{8\cdot80} : 8\cdot90/\frac{11\cdot30}{10\cdot70} : 9\cdot30$

$-$ 3·50, 0·15

Blue Pmma

A-2.3 Corneal Bitoric Lens

8·10/7·50	r_{01}/r_{02}
$-3\cdot50$, $-$ 1·50	$F'v$
9·3	ϕ_τ
0·15	t_c
9·40/8·80	r_{11}/r_{12}
7·50	ϕ_0
11·30/10·70	r_{21}/r_{22}
8·90	ϕ_1

Green Pmma

or

8·10 : 7·50/9·40 : 8·90/11·30 : 9·30
7·50 8·80 10·70

−3·50, − 1·50

0·15

Green Pmma

NOTE — The refractive power is written using the flatter meridian as the axis of the cylinder.

A-2.4 Corneal Front Toric Lens

7·95	r_0
−3·50, − 1·50 × 180	$F'v$
9·30	ϕ_T
0·30	t_c
9·20/7·60	r_1/ϕ_0
11·0/8·80	r_2/ϕ_1

Brown Pmma

1·5d prism axis 100

or

7·95 : 7·60/9·20 : 8·80/11·0 : 9·30

− 3·50, − 1·50 × 180

0·30

Brown Pmma

1·5d prism axis 100

A-2.5 Fused Segment Bifocal Lens

7·99	r_0
+ 1·50	$F'v$
9·0	ϕ_T
0·30	t_c
9·30/7·60	r_1/ϕ_0
11·30/8·60	r_2/ϕ_1

Clear Pmma

Add + 2·50, 1·5d prism axis 080 segment 7·0 wide, height 4·3 mm truncate 0·5 mm

or

7·99 : 7·60/9·30 : 8·60/11·30 : 9·0

+ 1·50, 0·30

Clear Pmma

Add + 2·50, 1·5d prism axis 080 segment 7·0 wide, height 4·3 mm truncate 0·5 mm

ANNEX B

(*Clause* 5.16)

RECOMMENDED METHOD FOR THE SPECIFICATION OF EDGE THICKNESS AND SHAPE

(This Annex is not a part of this standard but is included for information only).

In recognition of the need for a standard method to specify edge thickness and shape in the absence of suitable mechanical methods, the following categories of edge configurations are recommended.

The edge thickness is to be indicated by numerals 1 to 3, that is, 1 indicates a thin edge, 2 indicates a medium edge, and 3 indicates a thick edge (It is left to the manufacturer to provide the actual edge thickness values when requested).

Edge shape is to be indicated by letters A to C, that is, A indicates that the apex of the edge is 'towards the cornea', B indicates that the apex of the edge is on the centerline of the lens profile, and C indicates that the apex of the edge is 'away from the cornea'.

Thus a lens edge may be specified as 1B, 2B, 3A, etc. The illustrations shown in Fig. 2 may be used for descriptive purposes.

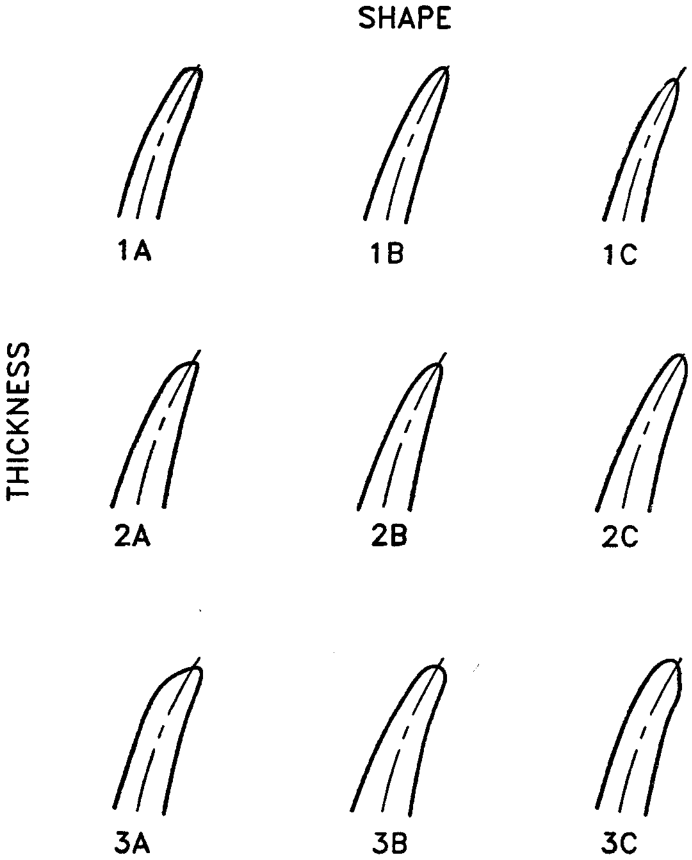


FIG. 2 CATEGORIES OF EDGE CONFIGURATIONS

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmoious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Revision of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Addition'. Comments on this Indian Standard may be sent to BIS giving the following reference:

Doc : No. MHD 5 (2370)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:
Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :	Telephone
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	331 01 31 331 13 75
Eastern : 1/14 C. I. T. Scheme VIII M, V. I. P. Road, Maniktola CALCUTTA 700054	37 84 99, 37 85 61 37 86 26, 37 86 62
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	53 38 43, 53 16 40 53 23 84
Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113	235 02 16, 235 04 42 235 15 19, 235 23 15
Western : Manakalaya, E9 MIDC, Marol, Andheri (East) BOMBAY 400093	632 92 95, 632 78 58 632 78 91, 632 78 92

Branch : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE. FARIDABAD. GHAZIABAD, GUWAHATI. HYDERABAD. JAIPUR. KANPUR LUCKNOW. PATNA. THIRUVANANTHPURAM.

Printed at Printwell Printers, Aligarh, India